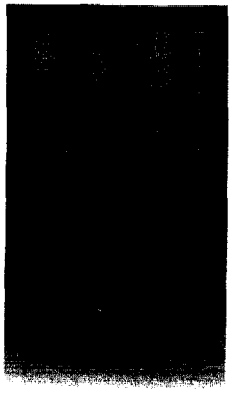

VirginiaCommonwealthUniversity

DIVISION OF
ADDICTION MEDICINE

1200 EAST BROAD STREET
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FAX: 804 828-9906
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September 28, 1999

Cynthia McCormick, M.D.
Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Dear Dr. McCormick:

I have been working in the Addictions Field for 30 years. During that time, I have been involved with maintenance therapies programs in the treatment of addiction. As you now, maintenance drugs for the treatment of addiction are some of the most studied and effective treatments and are among the most highly regulated drugs in the United States.

Having more than one maintenance therapy available to patients is important. Just as there is no one anti-hypertension agent that is effective for all patients, there probably is not one maintenance therapy for opioid dependence that is effective for all patients. Therefore, having methadone, LAAM and, hopefully in the future, buprenorphine we will be able to tailor the treatment appropriately to the patient's needs and response. In that regard, it would be essential that all maintenance therapies come under the same regulations. Therefore, I would propose that the regulations for LAAM be changed so that take-home privileges be allowed just as they are for methadone.

I understand the concern regarding diversion of take-home medications, however, the evidence does not support a significant diversion problem. In addition, if a patient in a program is allowed to take home a week's worth of medication the patient on LAAM would take home 2 doses rather than the six take-home doses that would occur with methadone. This would reduce the potential for diversion. As you know, addiction is an extremely difficult condition to treat and having an array of treatments available significantly increases our ability to provide appropriate treatment for patients. If taking one medication produces a burden that does not exist for other medications, then a patient may be reluctant to take the best medication for the treatment of his or her condition.

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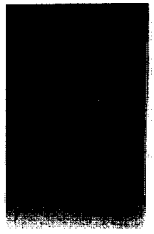
Unless there are compelling conditions, of which I am not aware, that would preclude the use of take-home for LAAM, I would strongly urge you to consider a change in the regulations to permit take-home doses of LAAM. If our ultimate goal is to get patients to return to a fully functional life where they are working, attending school or functioning at home, then we must remove the burden of tying patients to the clinic to get all their doses of medication. In states like Virginia, where there are few maintenance therapy programs, patients often have to travel two hours or longer to get to the clinic to obtain their medication. This significantly reduces their ability to return to the work force as productive citizens.

I am aware that the Center for Substance Abuse Treatment (CSAT) of the Substance Abuse Mental Health Services Administration (SAMHSA) is working on a proposal to have CSAT become the monitoring agency for methadone and LAAM maintenance programs. In the proposed new regulations, those patients taking LAAM will be able to have take home doses. I strongly urge that this change be implemented as soon as possible.

If you desire any additional information from, please feel free to call (804) 828-9914 or e-mail me at sschnoll@hsc.vcu.edu.

Peace,

Sidney H. Schnoll, M.D., Ph.D.
Professor, Departments of Internal Medicine and Psychiatry
Chairman, Division of Addiction Medicine



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